

What is claimed is:

1. A method of testing for effects of a condition on a drug sample, the method comprising:  
  
providing an array of drug samples;  
  
simultaneously exposing a first plurality of the drug samples in the array to a first controlled condition for a period of time within an exposure period;  
  
evaluating a plurality of the exposed drug samples at a first time using a non-destructive test; and  
  
evaluating the plurality of the exposed drug samples at a second time using the non-destructive test in order to determine whether the condition has an effect on one or more of the drug samples over time, wherein there is at least a portion of the exposure period between said first and second time.
2. The method of claim 1, wherein the drug samples of the array are different from each other.
3. The method of claim 2, further comprising simultaneously exposing a second plurality of the drug samples of the array to a second controlled condition different from the first controlled condition, wherein the second plurality of drug samples are exposed for a period of time within the exposure period.
4. The method of claim 2, further comprising exposing the first plurality of drug samples to a second controlled condition after exposure to the first controlled condition for a period of time within the exposure period.
5. The method of claim 2, further comprising simultaneously exposing the first plurality of drug samples to a second controlled condition.
6. The method of claim 1, wherein the drug samples provided in the array are the

same.

7. The method of claim 6, further comprising simultaneously exposing a second plurality of the drug samples in the array to a second controlled condition different from the first controlled condition for a period of time that is within the exposure period.
8. The method of claim 6, further comprising exposing the first plurality of drug samples in the array to a second controlled condition different from the first controlled condition for a period of time that is within the exposure period.
9. The method of claim 1, wherein the first controlled condition is an environmental condition selected from the group consisting of atmosphere, heat, humidity and light.
10. The method of claim 1, further comprising analyzing at least one of the exposed drug samples after the exposure period using a destructive test to determine the composition of the exposed drug samples.
11. The method of claim 10, wherein the destructive test is liquid chromatography.
12. The method of claim 10, wherein the destructive test is performed in parallel upon the selected exposed drug samples.
13. The method of claim 1, wherein the nondestructive test is selected from the group consisting of X-ray diffraction, birefringence, dynamic light scattering, fluorescence, Near Raman, Raman, Near IR, IR, and UV-Vis.
14. The method of claim 1, further comprising testing a plurality of the exposed drug samples with a second non-destructive test.
15. The method of claim 1, wherein the non-destructive testing on the plurality of exposed drug samples is performed in parallel.

16. The method of claim 1, wherein the exposure to at least one controlled condition is conducted in an environmental chamber.
17. The method of claim 16, wherein the first plurality of drug samples is exposed to controlled light, heat and humidity.
18. The method of claim 16, wherein the evaluating includes performing the non-destructive test inside the environmental chamber.
19. The method of claim 1, further comprising daughtering the array into at least four additional arrays before exposure, resulting in at least a first array, a second array, a third array, a fourth array and a fifth array.
20. The method of claim 19, wherein a plurality of the drug samples of the first array is exposed to a first controlled temperature condition, a plurality of the drug samples of the second array is exposed to a second controlled temperature condition different from the first temperature condition, a plurality of the drug samples of the third array is exposed to a first controlled humidity condition, a plurality of the drug samples of the fourth array is exposed to a second controlled humidity condition different from the first humidity condition and a plurality of the drug samples of the fifth array is exposed to a controlled light condition.
21. The method of claim 1, wherein the array is located on a common substrate.
22. The method of claim 21, wherein each drug sample of the array is located on a spatially discrete region of the substrate.
23. The method of claim 1, further comprising preparing the array of drug samples.
24. The method of claim 1, wherein the drug samples of the array contain no more than 10 mg of drug candidate.
25. The method of claim 1, wherein a plurality of the drug samples of the array

comprise an excipient selected from the group consisting of lubricants, surfactants, binders, fillers and disintegrants.

26. The method of claim 1, wherein the first controlled condition is a chemical exposure condition.
27. The method of claim 26, wherein exposing the samples to the condition comprises exposing the drug samples to at least one of the group consisting of acids, bases, radicals and oxidizers.
28. A method for evaluating the stability of drug samples when exposed to various controlled conditions, the method comprising:
  - providing an array of drug samples;
  - simultaneously exposing a plurality of the drug samples to at least one controlled environmental condition for an exposure period;
  - simultaneously exposing the plurality of the drug samples to at least one controlled chemical condition for the exposure period; and
  - evaluating any change of the exposed drug samples.
29. The method of claim 28, wherein the plurality of drug samples exposed to the controlled environmental condition and the plurality of drug compositions exposed to the chemical condition are drug candidates.
30. The method of claim 28, wherein the plurality of drug samples are exposed in a chamber.
31. The method of claim 28, wherein the controlled environmental exposure and the controlled chemical exposure occur simultaneously.
32. The method of claim 28, wherein at least two of the drug samples of the array are different from each other.

33. The method of claim 28, wherein at least one of the drug samples is exposed to a first controlled chemical condition and at least one other drug sample is exposed to a second controlled chemical condition different from the first controlled chemical condition.
34. The method of claim 28, wherein at least one of the drug samples is exposed to a first controlled environmental condition and at least one other drug sample is exposed to a second controlled environmental condition different from the first controlled environmental condition.
35. The method of claim 28, wherein the drug samples are drug compositions.
36. The method of claim 28, wherein at least one of the drug samples is a drug candidate and at least one of the drug samples is a drug composition.
37. The method of claim 28, wherein the change in the exposed drug samples is a change in chemical composition of an active pharmaceutical ingredient.
38. The method of claim 28, wherein the change in the exposed drug samples is a change in biological activity of the drug candidate.
39. The method of claim 28, wherein the change in the exposed drug samples is a change in component compatibility.
40. The method of claim 28, wherein a plurality of the drug samples of the array comprise a chemical selected from the group consisting of acids, bases, radicals and oxidizers.
41. The method of claim 28, wherein the controlled environmental condition is selected from the group consisting of heat, humidity and light.
42. The method of claim 28, wherein the drug samples of the array all have chemical or physical diversity.

43. The method of claim 28, wherein the drug compositions of the array are the same.
44. The method of claim 42, wherein at least one of the drug samples of the plurality of drug samples exposed to at least one controlled chemical condition is exposed to a first controlled chemical condition and at least one other drug sample of the plurality of drug samples exposed to at least one controlled chemical condition is exposed to a second controlled chemical condition different from the first controlled chemical condition.
45. The method of claim 43, wherein at least one of the drug samples of the plurality of drug samples exposed to at least one environmental condition is exposed to a first controlled environmental condition and at least one other drug sample of the plurality of drug samples exposed to at least one controlled environmental condition is exposed to a second controlled environmental condition different from the first controlled environmental condition.
46. The method of claim 42, wherein at least one of the drug samples of the plurality of drug samples exposed to at least one controlled environmental condition is exposed to a first controlled environmental condition and at least one other drug sample of the plurality of drug samples exposed to at least one controlled environmental condition is exposed to a second controlled environmental condition different from the first controlled environmental condition.
47. The method of claim 45, wherein at least one of the drug samples of the plurality of drug samples exposed to at least one controlled chemical condition is exposed to a first controlled chemical condition and at least one other drug sample of the plurality of drug samples exposed to at least one controlled chemical condition is exposed to a second controlled chemical condition different from the first

controlled chemical condition.

48. The method of claim 28, further comprising testing the exposed drug samples at least twice, wherein at least one of said tests is performed during the exposure period.
49. The method of claim 48, wherein the testing is non-destructive.
50. The method of claim 49, wherein the non-destructive test is selected from the group consisting of raman spectroscopy, X-ray diffraction, near infrared spectroscopy, dynamic light scattering and ultraviolet-visible spectroscopy.
51. The method of claim 48, further comprising conducting a destructive test after the exposure period.
52. The method of claim 48, wherein the testing is destructive.
53. The method of claim 28, further comprising preparing the array of drug samples.
54. The method of claim 28, further comprising daughtering the array into at least four additional arrays before exposure, resulting in at least a first array, a second array, a third array, a fourth array and a fifth array.
55. The method of claim 54, wherein a plurality of the drug samples of the first array is exposed to a first controlled temperature condition, a plurality of the drug samples of the second array is exposed to a second controlled temperature condition different from the first temperature condition, a plurality of the drug samples of the third array is exposed to a first controlled humidity condition, a plurality of the drug samples of the fourth array is exposed to a second controlled humidity condition different from the first humidity condition and a plurality of the drug samples of the fifth array is exposed to a controlled light condition.
56. The method of claim 28, wherein the array is located on a common substrate.

57. The method of claim 56, wherein each drug sample of the array is located on a spatially discrete region of the substrate.
58. The method of claim 28, wherein the drug compositions of the array contain no more than 10 mg of active pharmaceutical ingredient.
59. The method of claim 28, wherein a plurality of the drug samples of the array comprise an excipient selected from the group consisting of lubricants, surfactants, diluents, binders, fillers and disintegrants.
60. The method of claim 28, wherein a plurality of the drug samples of the array comprise a chemical selected from the group consisting of acids, bases, radicals and oxidizers.
61. The method of claim 28, further comprising placing the array of drug samples in a an exposure test chamber.
62. A process for developing a drug product, the process comprising:  
Screening an array of drug samples for both i) stability of drug candidates and ii) compatibility of drug composition components when the array is exposed to at least one condition using a common set of samples in a common set of experiments;  
formulating a clinical sample comprising a screened drug composition; and  
evaluating the formulated clinical sample in one or more clinical trials.
63. The method of claim 62, wherein the array has chemical and physical diversity.
64. The method of claim 62, further comprising screening a drug candidate for administration, distribution, metabolism, excretion and toxicity before screening the array.
65. The method of claim 62, wherein the experiments comprise evaluating any time dependent changes in the samples when exposed to at least one controlled



condition using at least one non-destructive test and at least one destructive test on each sample.

66. The method of claim 62, wherein each of the drug samples comprises a drug candidate and at least one additional component.
67. The method of claim 66, wherein each of the drug samples comprise an excipient.
68. The method of claim 66, wherein each of the drug samples comprises a drug candidate and at least two additional components.
69. The method of claim 62, wherein the screening comprises exposing the array of drug samples to a controlled environmental or chemical condition.
70. The method of claim 69, wherein the controlled environmental exposure is conducted in an environmental chamber.
71. The method of claim 69, wherein the controlled environmental condition is selected from the group consisting of, temperature, humidity, visible light, ultra violet light and infrared light.
72. The method of claim 69, wherein the controlled chemical condition is exposure to acidic, basic, oxidative or reductive environments.
73. A method for testing effects of a controlled exposure condition on a drug sample, the method comprising:
- providing a drug sample comprising less than 40 mg of drug candidate;
- exposing the sample to at least one controlled condition for an exposure period; and
- generating data from at least one type of test conducted on the sample at least twice with at least a portion of the exposure period being between the tests to determine if there has been any change in the sample.
74. The method of claim 73, wherein the sample comprises less than 20 mg of drug

candidate.

75. The method of claim 73, wherein the sample comprises less than 10 mg of drug candidate.

76. The method of claim 73, wherein the sample comprises less than 1 mg of drug candidate.

77. The method of claim 73, wherein the sample comprises less than 0.1 mg of drug candidate.

78. The method of claim 73, wherein the controlled condition is an environmental condition selected from the group consisting of temperature, humidity and light.

79. The method of claim 78, further comprising exposing the sample to a chemical condition during the exposure period.

80. The method of claim 73, further comprising determining the composition of the sample after the exposure period and comparing to the composition of the sample before the exposure period.

81. The method of claim 80, wherein the composition of the sample after the exposure period is determined using a destructive test.

82. The method of claim 81, wherein the destructive test is high performance liquid chromatography.

83. The method of claim 73, wherein the test is a non-destructive test.

84. The method of claim 83, wherein the non-destructive test is selected from the group consisting of raman spectroscopy, X-ray diffraction, near infrared spectroscopy, dynamic light scattering and ultraviolet-visible spectroscopy.

85. The method of claim 73, wherein the sample is exposed to at least two different controlled environmental conditions.

86. The method of claim 73, wherein the sample is exposed to at least three different controlled environmental conditions.
87. The method of claim 86, wherein the sample is exposed to the at least three different controlled environmental conditions simultaneously in an enclosure.
88. The method of claim 73, wherein the sample is part of an array of drug compositions.
89. A method for evaluating the possible effects of a controlled exposure condition on a drug sample, the method comprising:  
providing an array of drug samples on a single substrate;  
exposing the array and the substrate to at least one controlled condition for an exposure period; and  
evaluating the array of drug samples at least twice using one type of test with at least a portion of the exposure period being between the two tests to determine the effects of the exposure on the drug samples of the array, wherein the drug samples of the array remain on the substrate throughout the evaluation step.
90. The method of claim 89, further comprising placing the array of drug samples in an environmental chamber prior to the exposing step.
91. The method of claim 90, wherein the tests are conducted inside the environmental chamber.
92. The method of claim 90, wherein the array of drug samples is removed from the environmental chamber for testing the drug compositions, and replaced in the environmental chamber after the tests.
93. The method of claim 89, wherein the one type of test is a non-destructive test.
94. The method of claim 93, wherein the non-destructive test is selected from the

group consisting of raman spectroscopy, X-ray diffraction, near infrared spectroscopy, dynamic light scattering and ultraviolet-visible spectroscopy.

95. The method of claim 93, further comprising evaluating the composition of the array of drug samples after the exposure period using at least one destructive test.
96. The method of claim 95, wherein the destructive test is liquid chromatography.
97. The method of claim 95, wherein the at least one destructive test is conducted in parallel.
98. The method of claim 89, further comprising simultaneously exposing the array of drug samples to at least one controlled chemical condition.
99. The method of claim 89, further comprising daughtering the array into at least four additional arrays before exposure, resulting in at least a first array, a second array, a third array, a fourth array and a fifth array.
100. The method of claim 98, wherein a plurality of the drug samples of the first array is exposed to a first controlled temperature condition, a plurality of the drug samples of the second array is exposed to a second controlled temperature condition different from the first controlled temperature condition, a plurality of the drug samples of the third array is exposed to a first controlled humidity condition, a plurality of the drug samples of the fourth array is exposed to a second controlled humidity condition different from the first controlled humidity condition and a plurality of the drug samples of the fifth array is exposed to a controlled light condition.
101. The method of claim 100, wherein the at least one test is conducted in parallel.
102. The method of claim 89, wherein the at least one test is conducted in

parallel.

103. A method of research for possible effects of exposure conditions on a drug sample or a component thereof, the method comprising:

providing an array of drug samples;

simultaneously exposing two samples of the array of drug samples to a set of controlled exposure conditions for a period of time, wherein the controlled exposure conditions vary across the array;

testing the exposed samples; and

determining if there has been any change in the exposed drug samples.

104. The method of claim 103, further comprising placing the array of drug samples in an enclosure prior to exposure.

105. The method of claim 103, wherein the controlled conditions are environmental conditions selected from the group consisting of light, temperature and humidity.

106. The method of claim 103, wherein the array of drug samples are located on a common substrate.

107. The method of claim 103, wherein the method is software integrated.

108. The method of claim 103, wherein the testing is non-destructive.

109. The method of claim 103, wherein the testing is destructive.

110. The method of claim 103, wherein the testing comprises a non-destructive test conducted at least twice on the exposed samples during the period of time, and a destructive test conducted on the exposed samples after the period of time.

111. The method of claim 110, wherein the exposed samples are tested in parallel.

112. A method for testing a drug sample, the method comprising:  
providing the drug sample;  
simultaneously exposing the sample to controlled light, humidity and temperature conditions in an environmental chamber for an exposure period;  
testing the sample; and  
determining if there has been any change in the sample over time.
113. The method of claim 112, wherein the sample comprises less than 40 mg of active pharmaceutical ingredient.
114. The method of claim 112, wherein the sample comprises less than 20 mg of active pharmaceutical ingredient.
115. The method of claim 112, wherein the sample comprises less than 10 mg of active pharmaceutical ingredient.
116. The method of claim 112, wherein the sample comprises less than 1 mg of active pharmaceutical ingredient.
117. The method of claim 112, wherein the sample comprises less than 0.1 mg of active pharmaceutical ingredient.
118. The method of claim 112, wherein the controlled light, temperature and humidity conditions change over the exposure period.
119. The method of claim 112, wherein the testing is non-destructive.
120. The method of claim 112, wherein the testing is destructive.
121. The method of claim 112, wherein the testing comprises a non-destructive test conducted at least twice on the exposed samples during the period of time, and a destructive test conducted on the exposed samples after the period of time.
122. A method for generating data for analyzing any time dependent changes

in a drug sample over time, the method comprising:

providing a first array of drug samples, a second array of drug samples, a third array of drug samples, a fourth array of drug samples, and a fifth array of drug samples;

simultaneously exposing the plurality of the first array of drug samples to a first controlled temperature setting for a period of time within an exposure period;

simultaneously exposing plurality of the second array of drug samples to a second controlled temperature setting for a period of time in the exposure period;

simultaneously exposing a plurality of the third array of drug samples to a first controlled humidity setting for a period of time in the exposure period;

simultaneously exposing a plurality of the fourth array of drug samples to a second controlled humidity setting for a period of time in the exposure period;

simultaneously exposing a plurality of the fifth array of drug samples to a controlled light setting for a period of time in the exposure period;

testing all of the arrays with a non-destructive test at least twice during the exposure period; and

generating data from the non-destructive tests for each array of drug samples.

123. The method of claim 122, further comprising placing the first array in a first environmental chamber prior to the exposure period, placing the second array in a second environmental chamber prior to the exposure period, placing the third array in a third environmental chamber prior to the exposure period, placing the fourth array in a fourth environmental chamber prior to the exposure period, and placing the fifth array in a fifth environmental chamber prior to the exposure period.

124. The method of claim 122, wherein arrays are tested in the environmental

chambers.

125. The method of claim 122, wherein the arrays are removed from the environmental chambers for testing and are placed back in the environmental chambers after testing.
126. The method of claim 122, wherein the first, second, third, fourth and fifth arrays are exposed simultaneously.
127. The method of claim 122, wherein the first, second, third, fourth and fifth arrays are tested simultaneously.
128. The method of claim 122, wherein at least two samples are simultaneously tested.
129. The method of claim 122, further comprising testing all of the arrays with a destructive test after the exposure period in order to determine the chemical composition of the drug composition samples; and determining if there has been a change in the samples over time.
130. A data file generated according to the methods of claims 1 to 129 comprising a set of non- destructive test data generated over time.
131. A computer program product embodied on a computer-readable medium for testing effects of a condition on a drug sample, the product including instructions operable to cause data processing apparatus operating in combination with an automated materials-handling device to perform operations comprising: simultaneously exposing a first plurality of drug samples in an array of drug samples to a first controlled condition for a period of time within an exposure period; evaluating a plurality of the exposed drug samples at a first time using a non-destructive test; and



evaluating the plurality of the exposed drug samples at a second time using the non-destructive test, at least a portion of the exposure period occurring between the first time and the second time; and

based on the evaluating, determining an effect of the controlled condition on one or more of the drug samples over time.

132. The computer program product of claim 131, further comprising instructions operable to cause the materials-handling device to perform further operations comprising:  
preparing the array of drug samples.

133. A computer program product embodied on a computer-readable medium for testing effects of a condition on a drug sample, the product including instructions operable to cause data processing apparatus to:  
receive first test data representing results of a non-destructive testing performed at a first time on a first plurality of drug samples in an array of drug samples; the first plurality of drug samples being simultaneously exposed to a first controlled condition for a period of time within an exposure period;  
receive second test data representing results of the non-destructive testing performed at a second time on the first plurality of drug samples, at least a portion of the exposure period occurring between the first time and the second time;  
based on the first test data and the second test data, determine an effect of the controlled condition on one or more of the drug samples over time.

134. A computer program product tangibly embodied in an information carrier for evaluating the stability of drug samples when exposed to a plurality of controlled conditions, the product including instructions operable to cause data

processing apparatus operating in combination with an automated materials-handling device to perform operations comprising:

simultaneously exposing a plurality of drug samples in an array of drug samples to at least one controlled environmental condition for an exposure period;

simultaneously exposing the plurality of the drug samples to at least one controlled chemical condition for the exposure period; and

receive test data for a plurality of tests performed on the plurality of drug samples; and

based on the test data, identifying a change in one or more of the drug samples during the exposure period.